



April 4, 2005
Gary M. Jackson
Assistant Administrator for Size Standards
Office of Size Standards
Small Business Administration
409 Third Street, SW
Washington, DC 20416

Re: Proposed Rulemaking Affecting SBIR Funding

Dear Mr. Jackson:

On behalf of Alimmune LLC, I want to thank you for the opportunity to comment on the Small Business Administration's (SBA) Advance Notice of Proposed Rulemaking (ANPRM) regarding the participation of businesses in the SBIR program that are majority-owned by one or more venture capital companies (VCC).

Alimmune typifies the small business that the SBIR program was created to help, a small business working to commercialize new technologies in biotechnology. Companies such as ours normally receive SBIR grants to fuel the research and development that lead to the commercialization of a technology. Along with future SBIR funding, our company hopes to receive additional crucial financial support from venture capital firms and other similarly situated entities. Without such financial support it is unlikely our technology would be fully commercialized. It is for this reason I believe it is vital that small businesses such as ours be allowed to participate in the SBIR grant program.

Alimmune has committed significant resources to developing therapeutics against the CD45 isoform, CD45RB. CD45 is the most abundant antigen found on B and T cells and is an ideal target for human antibody-based therapeutics. Antibodies against CD45RB are potent single-agent immune-modulating therapeutics that can be used to treat autoimmune diseases and to prevent organ transplant rejection.

We understand the 51% Rule now allows an SBIR award recipient to be owned by a VCC, as long as the VCC is itself owned and controlled by U.S. individuals. Alimmune has received funds, and expects to receive further funds, from VCCs that are not, in fact, owned or controlled by U.S. individuals. Some of these VCCs are, or could be owned by, a nonprofit entity such as a university or research institution. These entities may differ in structure or ownership from typical VCCs; however, they have similar objectives of encouraging product development by small companies. Additionally, most, if not all, nonprofit VCCs often make investments to advance the objectives of the Bayh-Dole Act.

We firmly believe that companies in which nonprofit VCCs invest should be able to participate in the SBIR grant program. **Thus, we believe that the SBA should (1) provide an exclusion from affiliation with VCCs in determining small business eligibility and (2) include nonprofit related VCC entities within the scope of the definition of VCC considered by the SBA in its rule making.**

I appreciate the opportunity to comment on this important matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Gino Di Sciullo". The signature is fluid and cursive, with a large initial "G" and "D".

Gino Di Sciullo, Ph.D.
Manager
Alimmune LLC